

Application No.: 10/698,100  
Amendment Dated: November 22, 2005

In the Claims:

The current claim set of the application is presented below. Indications as to the status of the claims ("original," "currently amended," "canceled," "previously presented," "not entered," "new," etc.) appear in parentheses after the claim number. Deletions are identified in bold with double brackets and strikethrough (e.g. ~~[[deletion]]~~) and new text is identified in bold with underlining (e.g. new language).

1. (Currently amended) A method comprising:  
inserting a shaft into a urethra of a patient in proximity to a prostate gland of the patient;  
extending a needle from a side of the shaft to pierce the prostate gland in a first location, the needle including a lumen; ~~[[and]]~~  
injecting botulinum toxin ~~[[a denervating agent]]~~ into the prostate gland through the lumen of the needle;  
retracting the needle from the first location;  
moving the shaft relative to the prostate gland;  
extending the needle to pierce the prostate gland in a second location;  
injecting a second dose of the botulinum toxin through the lumen to the second location;  
wherein the total dosage of botulinum toxin delivered to the prostate is from approximately 50 units to approximately 400 units.
2. Canceled
3. (Original) The method of claim 1, wherein an endoscope is housed within a substantially transparent distal tip of the shaft, the method further comprising guiding the shaft in proximity to the prostate gland using images generated by the endoscope.
4. (Original) The method of claim 1, wherein the shaft includes a distal tip that defines an offset curvature to improve navigation of the shaft through the urethra into proximity to the prostate gland.

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5. Cancelled
6. (Currently amended) The method of claim 1 ~~[[5]]~~, further comprising extending the needle to a first depth at the first location and extending the needle to a second depth at the second location, wherein the first and second depths are different.
7. (Currently amended) The method of claim 1, further comprising:  
extending the needle to pierce the prostate gland in a plurality of locations;  
injecting a plurality of doses of the botulinum toxin ~~[[denervating agent]]~~ through the lumen to the plurality of locations.
8. Cancelled
9. Cancelled
10. Cancelled
11. (Original) The method of claim 1, further comprising injecting each of the doses prior to removing the shaft from the urethra of the patient.
12. Cancelled
13. (Currently amended) A device for delivering a denervating agent to a prostate gland comprising:  
a shaft for insertion into a urethra in proximity to the prostate gland, the shaft defining a hole on a side of the shaft in proximity to a distal tip of the shaft;  
a needle within the shaft, the needle defining a lumen, wherein a distal end of the needle is extendable through the hole out the side of the shaft;

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an actuator to cause the needle to extend through the hole out the side of the shaft into the prostate gland when the shaft is inserted in proximity to the prostate gland, wherein the needle is spring-loaded such that when the actuator causes the needle to extend through the hole, the needle is spring biased into the prostate gland; and

a denervating agent delivery assembly to cause the denervating agent to pass through the lumen and into the prostate gland when the shaft is inserted in proximity to the prostate gland and the needle is extended through the hole out the side of the shaft into the prostate gland.

14. Cancelled

15. (Original) The device of claim 13, wherein the denervating agent includes botulinum toxin.

16. (Original) The device of claim 13, further comprising an endoscope housed within the shaft, wherein the distal tip of the shaft comprises a substantially transparent material such that the endoscope can view through the distal tip.

17. (Original) The device of claim 13, wherein the distal tip of the shaft defines an offset curvature to improve navigation of the shaft through the urethra into proximity to the prostate gland.

18. (Original) The device of claim 13, wherein the actuator comprises a slide bar.

19. (Original) The device of claim 18, wherein the slide bar allows for advancement of the needle to various depths.

20. (Original) The device of claim 13, the denervating agent delivery assembly includes a reservoir to hold the denervating agent and a second actuator to cause the denervating agent to flow from the reservoir through the lumen.

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21. (Original) The device of claim 20, wherein the second actuator comprises a plunger.
22. (Original) The device of a claim 20, further comprising a hub and a fluid line for attachment of the reservoir to the needle.
23. (Original) The device of claim 13, wherein the denervating agent delivery assembly includes a first reservoir to hold a substantial amount of the denervating agent and a second reservoir to hold a discrete dose of the denervating agent, wherein the second reservoir refills with another discrete dose of the denervating agent from the first reservoir following actuation of the second actuator.
24. (Original) The device of claim 13, wherein the denervating agent includes botulinum toxin, wherein the first reservoir holds greater than approximately 4 milliliters of the botulinum toxin, and wherein the second reservoir holds less than approximately 1 milliliter of the botulinum toxin.
25. (Original) The device of claim 13, wherein the denervating agent delivery assembly includes a second actuator, a pump, and a reservoir, wherein upon actuation of the second actuator the pump causes delivery of the denervating agent from the reservoir through the lumen.
26. (Original) The device of claim 25, wherein the first actuator comprises a slide bar and the second actuator comprises a switch.
27. (Original) The device of claim 13, further comprising a plurality of needles within the shaft, each of the plurality of needles defining a respective lumen, wherein a distal end of a given one of the needles is extendable through a respective one of a plurality of holes formed on the side of the shaft;
- wherein the actuator causes the plurality of needles to extend through the plurality of holes into the prostate gland when the shaft is inserted in proximity to the prostate gland; and

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wherein the denervating agent delivery assembly causes the denervating agent to pass through the respective lumens of the plurality of needles into the prostate gland when the shaft is inserted in proximity to the prostate gland and the plurality of needles are extended through the plurality of holes into the prostate gland.

28. (Original) The device of claim 13, wherein the shaft is semi-flexible.

29. (Currently amended) A device for delivering a denervating agent to a prostate gland comprising:

a shaft for insertion into a urethra in proximity to the prostate gland, the shaft defining a hole on a side of the shaft in proximity to a distal tip of the shaft;

a needle within the shaft, the needle defining a lumen, wherein a distal end of the needle is extendable through the hole out the side of the shaft;

means for causing the needle to extend through the hole out the side of the shaft into the prostate gland when the shaft is inserted in proximity to the prostate gland

means for spring biasing the needle into the prostate gland; and

means for causing a denervating agent to pass through the lumen and into the prostate gland when the shaft is inserted in proximity to the prostate gland and the needle is extended through the hole out the side of the shaft into the prostate gland.

30. Cancelled